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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/607,142	06/29/2000	Joel Cherry	5443.424-US	7060

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EXAMINER

MAHATAN, CHANNING

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 02/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/607,142

Applicant(s)

CHERRY ET AL.

Examiner

Channing S. Mahatan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 5 and 35-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5 and 35-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 18 July 2002 is: a) ☒ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). 14.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_. 6) ☐ Other:

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## DETAILED ACTION

### *APPLICANTS' ARGUMENTS*

Applicants' arguments in Paper No. 10, filed 18 July 2002, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application. Further, applicants' "Notice of Appeal to the Board of Patent Appeals and Interferences" is found moot, since as indicated in an interview with applicants' representative, on 25 July 2002, prosecution of the pending application will be reopened.

### *CLAIMS UNDER EXAMINATION*

Claims herein under examination are claims 5 and 35-40.

### **Claims Rejected Under 35 U.S.C. § 112 1<sup>st</sup> Paragraph**

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 U.S.P.Q. 546 (B.P.A.I. 1986) and reiterated by the Court of Appeals in In re Wands, 8 U.S.P.Q.2d 1400 at 1404 (C.A.F.C. 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the

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art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, sufficient amounts for a prima facie case are discussed below.

*LACK OF ENABLEMENT*

Claims 5 and 35-40 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 5 (lines 7-9), 35 (lines 1-4), and all claims dependent therefrom recites the step "identifying an amino acid residue which is within 15 Å (10Å; in instant claim 35) from an active site residue of the parent amylase in the three-dimensional structure of said parent, and which is involved in electrostatic or hydrophobic interactions with an active site residue" which is not enabled and thus failing to provide guidance to practice. While it is acknowledged that the specification recites the broad general identifying step as in claim 5 (page 9, lines 28-32 of the Specification) and the "Changing the pKa of the active site residues is achieved, e.g., by changing the electrostatic interaction or hydrophobic interaction between function groups of amino acid side chains of a given amino acid residue and its close surroundings." Absent from the specification are procedures/steps by which active site residues are identified based upon electrostatic or hydrophobic interactions and are thereby changed/substituted. Additionally, applicants have failed to identify/indicate the residues which are 15 Å from the active site and are involved in electrostatic or hydrophobic interactions with an active site residue. It is

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acknowledged that the specification indicates residues that are 10 or 15 Å from the active site for SEQ ID NO: 2 (page 10, lines 2-24), however, there is no indication that any of these residues are involved in electrostatic or hydrophobic interactions with an active site residue. Further, applicants have failed to indicate the amino acid residue which when utilized to substitute with the said amino acid residue would change the electrostatic and/or hydrophobic surroundings of an active site, and which can be accommodated in the structure. An individual skilled in the art would not understand how to perform said step unless some type of information/procedure is set forth.

Claim 5 (lines 4-6) and all claims dependent therefrom recites the step “modeling the parent alpha-amylase on the three-dimensional structure of amino acid residues 1-686 of SEQ ID NO: 2 depicted in the Appendix to produce a three-dimensional structure of the parent alpha-amylase” which is not enabled and thus failing to provide guidance to practice. General reference to modeling program (page 7, lines 26-36) is not specific guidance; particularly for modeling a “...parent maltogenic alpha-amylase ... which is at least 70% identical...” Further, none of the examples provided for in the specification (pages 33-47) exemplify the claimed method of constructing a variant of a parent maltogenic alpha-amylase which is at least 70% identical to SEQ ID NO: 2. Without specific guidance on the method steps involved in modeling a parent maltogenic alpha-amylase an individual skilled in the art would not understand how to perform said step unless some type specific procedure (rather than a general broad concept) is set forth.

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*LACK OF WRITTEN DESCRIPTION*

Claims 5, 35, and all claims dependent therefrom are rejected under 35 U.S.C. § 112 1<sup>st</sup> Paragraph for failing to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize applicants were in possession of the claimed invention. As reiterated from the previous office action (with further clarification), there is no disclosure regarding all three-dimensional (i.e. coordinates) crystal structure (i.e. parent maltogenic alpha-amylase ... which is at least 70% identical to amino acid residues 1-686 of SEQ ID NO: 2) other than an  $\alpha$ -amylase having the three-dimensional structure of SEQ ID NO: 2 (i.e. parent maltogenic alpha-amylase which is 100% identical). Additionally, the active site of the parent alpha amylase is undefined; lacking is the specific sequence(s), atomic coordinates, and the active site location(s) within the "parent alpha amylase ... which is at least 70% identical ...".

**Claims Rejected Under 35 U.S.C. § 112 2<sup>nd</sup> Paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 35-40 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

*VAGUE AND INDEFINITE*

Claim 5 (lines 11-12) and all claims dependent therefrom recites the term "which can be accommodated in the structure" which is vague and indefinite. It is unclear by what limitation applicants refer to as "accommodated", wherein "accommodated" implies a degree of

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accommodation (i.e. a value, criteria, etc). Applicants can resolve this issue by particularly pointing out what the limitations of "accommodated in the structure" refers to. Clarification of the metes and bounds of the limitation, via clearer claim wording, is required.

Claim 5 (line 13) and all claims dependent therefrom recites the step "optionally repeating steps b) and c) recursively which is vague and indefinite. The step is unclear as to the limitation provided for by "optionally repeating". For example, if steps b) and c) are repeated: 1) the number of times is not defined; nor 2) the criteria by which the option is set forth (i.e. when is the option to be performed). Clarification of the metes and bounds of the limitation, via clearer claim wording, is required.

Claim 5 (lines 14-15) and all claims dependent therefrom recites the step "optionally, making alterations each of which is an insertion, a deletion or a substitution of an amino acid residue at one or more positions other than c)," which is vague and indefinite. The step is unclear as to the limitation provided for by "optionally making alterations". For example, if alterations are made: 1) the number of times is not defined; nor 2) the criteria by which the option is set forth (i.e. when is the option to be performed). Clarification of the metes and bounds of the limitation, via clearer claim wording, is required.

Claim 5 (line 18) and all claims dependent therefrom recites the step "optionally repeating steps a) - g) recursively; and" which is vague and indefinite. It is unclear as to whether "optionally repeating" the steps (particularly beginning with step a)) utilizes the "old" variant (i.e. from step g) versus "new" variant (i.e. utilizing a new parent alpha-amylase all together). Clarification of the metes and bounds of the limitation, via clearer claim wording, is required.

Claim 5 and all claims dependent therefrom are indefinite due to the lack of clarity of the claim language failing to recite a final process step, which agrees back with the preamble. The preamble states that it is "a method of constructing a variant of a parent maltogenic alpha-amylase ...", however the claim recites a final step of "selecting a variant having an altered pH dependent activity as compared to the parent amylase". While minor details are not required in method/process claims, at least the basic step must be recited in a positive, active fashion. Clarification of the metes and bounds of the claim is requested via clearer claim wording.

*OBJECTION OF DISCLOSURE*

The disclosure is objected to because of the following informalities:

The lengthy specification has several notations to a polypeptide/amino acid sequence which is stated to be SEQ ID NO: 1, however, the pending claims and sequence listing conflict with said SEQ ID NO. Applicants are requested to review the application and correct SEQ ID NO: 1 to SEQ ID NO: 2. Further, applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

**Appropriate Correction Is Required.**

**No Claim Is Allowed.**

*EXAMINER INFORMATION*

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and



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1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Channing S. Mahatan whose telephone number is (703) 308-2380. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina M. Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date:

*February 4, 2003*

Examiner Initials:

*CSM*

*Marianne P. Allen*  
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